

EXHIBIT D

STATEMENT OF THE ISSUES

Topic a: The Standard Operating Procedures (SOP) associated with design and development of the Devices.

Response and Objections to Topic a: Federal Rule of Civil Procedure 30(b)(6) requires that the deposition notice “describe with reasonable particularity the matters for examination.” The purpose of this requirement is to permit the deponent to be able to prepare properly for the deposition, as the deponent may be asked to testify on matters outside of his or her personal knowledge. Defendants object that this topic is overbroad and unduly burdensome and provides insufficient notice under Rule 30(b)(6). The design and development of the devices were long term projects, taking a total of more than a dozen years from TVT to TVT Exact and Abbrevio. Thus, the Standard Operating Procedures associated with each device were revised multiple times over the course of this time period. Defendants object that: (a) it is impossible for any witness to testify about every version of the Standard Operating Procedures associated with each device; (b) this topic is overbroad since there will be numerous standard operating procedures applicable to the design of the Devices that have no bearing on this litigation; and (c) this is an improper topic for an oral deposition as the information can be more efficiently transmitted by a document production regarding the particular standard operating procedures that Plaintiffs seek to discovery.

Subject to and without waiving these Specific Objections, Defendants will produce a witness or witnesses whose testimony will address the most recent Standard Operating Procedure associated with the design and development of the Devices and answer questions to the best of his or her ability regarding this improper request.

Topic b: The complete design history file for the Devices, including each component part of the file, the custodian responsible for the file and the maintenance of the file.

Response and Objections to Topic b: During a meet and confer held on March 22, 2013, and in correspondence exchanged prior to that meet and confer, Defendants objected that this topic is overbroad, is not stated with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). It is Defendants' understanding that, as a result of that meet and confer, Plaintiffs agreed that this topic is overly broad and reformulated it to seek testimony regarding the following: (1) what makes up the Design History File ("DHF"); (2) what are the component parts of the DHF; (3) the custodian of the DHF; (4) how the DHF is maintained; and (5) the Bates ranges for each DHF.

Defendants will produce a witness to testify in regard to items 1-4 of the reformulated topic. But Defendants object that item 5 is an inappropriate subject for a 30(b)(6) deposition. Each of the products at issue has a design history file. These design history files are voluminous and, in total, comprise more than ten thousand pages of material. Due to the size of these documents, no company witness could possibly testify as to the completeness of a particular DHF presented to him or her. Moreover, the individual whom Defendants will designate regarding the topic of DHFs played no role in Bates stamping the documents and cannot personally verify the accuracy of any produced copy.

Defendants are more than willing to provide Plaintiffs a written discovery response that identifies the Bates ranges of each DHF to satisfy any concern Plaintiffs may have about the completeness of the DHFs produced.

Topic c: Members and procedures of the Product Development Team for the Devices.

Response and Objections to Topic c: Defendants object that this topic is overbroad and unduly burdensome and provides insufficient notice under Rule 30(b)(6). The design and development of the Devices were long-term projects; the members and procedures of the Product Development Team for the Devices changed over time encompassing more than twelve years; and this information is reflected in the design history files – which encompass more than ten thousand pages of material. It is impossible for any witness to testify about the members and procedures of the Product Development Team for seven products. Defendants further object that the topic is vague and ambiguous. Due to the long-term nature of the projects, as well as the fact that many individuals played only a tangential role in those projects, various witnesses may consider the same individual to be “on” or “not on” the design team for a particular device. Finally, Defendants object that the information sought in this topic is more readily available to Plaintiffs from other sources. Such information is included in the design history files, which Defendants have already produced to Plaintiffs as they were kept in the ordinary course of business and in an electronically searchable format. *See, e.g., Catt v. Affirmative Ins. Co.*, No. 2:09-CV-243, 2009 WL 1228605 at * (N.D. Ind. Apr. 30, 2009) (finding deposition topic that sought general testimony about documents produced “too broad and not described with reasonable particularity”).

As part of the meet and confer process, Defendants identified specific documents (such as the Design and Development Plan, Team meeting minutes, and lab reports that list individuals working on the projects. As a result, Plaintiffs can ascertain the identities of the individuals who worked on these projects without undue burden.

Topic i: All product names of the Devices.

Response and Objections to Topic i: Defendants object that the information sought is more readily available to Plaintiffs from other sources. Such information is included in the design history files, which Defendants have already produced to Plaintiffs in the manner they were kept in the ordinary course of business and in an electronically searchable format. *See, e.g., Catt v. Affirmative Ins. Co.*, No. 2:09-CV-243, 2009 WL 1228605 at * (N.D. Ind. Apr. 30, 2009) (finding deposition topic that sought general testimony about documents produced “too broad and not described with reasonable particularity”).

In an effort to compromise, Defendants will, in advance of the deposition, provide Plaintiffs with a list of the project names it has identified for the Devices to date.

Topic s: Any patents relating to the Devices and their predecessor mesh products.

Response and Objections to Topic s: As a result of the parties’ meet and confer held on March 22, 2013, Plaintiffs agreed to limit this topic to the Devices identified in the Notices (i.e., TVT, TVT-AA, TVT-O, TVT-Secure, TVT Exact and TVT-Abbrevio). Additionally, during that same meet and confer and in response to Defendants’ objection that the topic was too broad, Plaintiffs indicated that their areas of interest were identity of the inventor, the name of the patent holder, a description of the patent, and testimony regarding the patents for the Devices from a “design perspective.”

Defendants maintain their objection that this topic, as limited by Plaintiffs, fails to describe with reasonable particularity the matters for examination, as required by Rule 30(b)(6). In an effort to compromise, however, Defendants will produce a witness to testify about the United States patents directly related to the Devices. For each of these patents, Defendants’ designee will be prepared to testify as a corporate representative regarding the identity of the

inventor, the name of the present holder of each patent, and the patent's description. Additionally, the designee will be prepared to testify about the patents from a "design perspective" and to his or her personal knowledge concerning each of the patents at issue.

Finally, Defendants note that the Devices are the subject of patent filings in ex-United States jurisdictions. Defendants do not read the Notices to seek testimony concerning ex-United States patents. To the extent the Notices do seek such testimony, Defendants object to the production of any information regarding ex-United States patents (or patent filings) as not reasonably calculated to lead to the discovery of admissible evidence, unreasonably burdensome, and equally available to Plaintiffs, to the extent such filings are matters of public record.

Topic kk: As they relate to design control and validation, the manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization.

Response and Objections to Topic kk: Defendants object that: (a) it is impossible for any witness (or even multiple witnesses) to testify regarding the "the manufacturing processes" for all seven devices over a period of more than a dozen years; (b) this topic is dramatically overbroad since there will be numerous manufacturing processes related to the Devices that have no bearing on this litigation; and (c) this is an improper topic for an oral deposition as this information can be more efficiently transmitted by a document production regarding the particular communications Plaintiffs seek to discover.

In the meet and confer held March 22, 2013, Plaintiffs advise Defendants that this topic seeks testimony regarding the process by which the Prolene mesh is manufactured, woven, tested, and sterilized, as well as similar "type" information regarding the tools that accompany each device. As explained during that meet and confer, Defendants will produce a witness or

witnesses who are knowledgeable about the manufacturing processes in general and will be prepared to discuss this topic at a high level. To the extent Plaintiffs elect to drill down on a particular topic in greater detail, Defendants may have to identify additional witnesses to address those topics.

Request No. 5(n): The following documents for the design and development of the Devices, including but not limited to: All company policies and procedures that apply to or relate to the Design History File.

Response and Objections to Request No. 5: Defendants object that this request is overbroad and unduly burdensome, in that many of its subparts include no temporal limitation and are not limited to the Devices. Defendants further object that the request is vague and ambiguous because, among other things, the term “Franchise Procedure” is undefined. Finally, Defendants object that certain of the documents sought in this request are more readily available to Plaintiffs from other sources. Defendants have, for example, already produced to Plaintiffs the complete design history files as they were kept in the ordinary course of business in an electronically searchable format. Without waiving these objections, below are the Bates ranges of previously produced documents that Defendants believe are responsive to each subpart of this request:

. . . .

n. All company policies and procedures that apply to or relate to the Design History File;

Defendants will continue to search to determine whether any documents responsive to this Request have been produced or should be produced and invite Plaintiffs to meet and confer on this issue.